PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference Y05017-PCT	FOR FURTHER ACTION	See item 4 below				
International application No. PCT/JP2005/005377	International filing date (day/month/year) 24 March 2005 (24.03.2005)	Priority date (day/month/year) 25 March 2004 (25.03.2004)				
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237						
Applicant Astellas Pharma Inc.						

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).						
2.	This REPORT consists of a total of 5 sheets, including this cover sheet.						
	In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.						
3.	3. This report contains indications relating to the following items:						
	Box No. I	Basis of the report					
	Box No. II	Priority					
	Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability						
	Box No. IV	Lack of unity of invention	n				
Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive applicability; citations and explanations supporting such statement			r Article 35(2) with regard to novelty, inventive step or industrial d explanations supporting such statement				
	Box No. VI	No. VI Certain documents cited					
	Box No. VII	Certain defects in the international application					
	Box No. VIII	Certain observations on the	ne international application				
4.	4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis.2).						
			Date of issuance of this report 19 October 2006 (19.10.2006)				
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland		lombettes	Authorized officer Masashi Honda				
Facsimile No. +41 22 338 82 70			e-mail: pt08@wipo.int				

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

TRANSLATION From the INTERNATIONAL SEARCHING AUTHORITY WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1) Date of mailing (day/month/year) Applicant's or agent's file reference FOR FURTHER ACTION Y05017-PCT See paragraph 2 below Priority date (day/month/year) International application No. International filing date (day/month/year) PCT/JP2005/005377 24.03.2005 25.03.2004 International Patent Classification (IPC) or both national classification and IPC Applicant Astellas Pharma Inc. This opinion contains indications relating to the following items: Box No. I Basis of the opinion Box No. II Priority Non-establishment of opinion with regard to novelty, inventive step and industrial applicability Box No. III Box No. IV Lack of unity of invention Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial Box No. V applicability; citations and explanations supporting such statement Box No. VI Certain documents cited Box No. VII Certain defects in the international application Box No. VIII Certain observations on the international application **FURTHER ACTION** If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered. If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later. For further options, see Form PCT/ISA/220. For further details, see notes to Form PCT/ISA/220. Authorized officer Name and mailing address of the ISA/JP Telephone No. Facsimile No.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2005/005377

Box	No. I	Basis of this opinion
1.		regard to the language, this opinion has been established on the basis of the international application in the language in which it was unless otherwise indicated under this item.
		This opinion has been established on the basis of a translation from the original language into the following language
	-	, which is the language of a translation furnished for the purposes of international search (under
2	W	Rule 12.3 and 23.1(b)).
2.		regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed attention, this opinion has been established on the basis of:
	a.	type of material
		a sequence listing
		table(s) related to the sequence listing
	b.	format of material
		in written format
		in computer readable form
	c.	time of filing/furnishing
		contained in the international application as filed.
		filed together with the international application in computer readable form.
		furnished subsequently to this Authority for the purposes of search.
3.		In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filled or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4.	Add	itional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/005377

Box No. V Reasoned statement under Rule 43bls.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement				
1.	Statement			
	Novelty (N)	Claims	2, 9-12	YES
		Claims	1, 3-8	NO
	Inventive step (IS)	Claims		YES
		Claims	1-12	NO
	Industrial applicability (IA)	Claims	1-12	YES
		Claims		NO

2. Citations and explanations:

Document 1) WO 96-20194 A1 (Yamanouchi Pharmaccutical Co., Ltd.) 4 July 1996 WO 03/103659 A1 (Yamanouchi Pharmaccutical Co., Ltd.) 18 December 2003

Document 3) JP 2003-261439 A (Asahi Kasei Corp.) 16 September 2003

Document 4) International Journal of Pharmaceutics, 1990, 62, p. 87-95

Document 5) JP 9-71761 A (Ajinomoto Co., Inc.) 18 March 1997

Document 6) JP 62-136240 A (Kabushiki Kaisha Hayashibara Seibutsu Kagaku

Kenkyujo) 19 June 1987

[1] Based on the description in document 1 cited in the international search report, the inventions of claims 1 and 3-8 lack novelty and an inventive step.

Document 1 describes crystalline solifenacin and a solid composition such as a tablet and the like as a composition containing solifenacin. Therefore, the invention of claim 1 is one and the same as the invention described in document 1. In addition, the inventions of claims 3-8 of this application are ones that specify the process for producing the invention of claim 1, but specification of the production process cannot distinguish the inventions of claims 3-8 of this application from the invention described in document 1 as a composition containing solifenacin.

[2] Based on the description in document 2 cited in the international search report, the inventions of claims 1 and 3-8 lack novelty and an inventive step.

EXAMPLE 14 of document 2 describes a capsule preparation containing solifenacin. Therefore, the invention of claim 1 is one and the same as the invention described in document 2. In addition, the inventions of claims 3-8 of this application are ones that specify the process for producing the invention of claim 2, but specification of the production process cannot distinguish the inventions of claims 3-8 of this application from the invention described in document 2 as a composition containing solifenacin.

[3] Based on the description in document 3 cited in the international search report, the inventions of claims 1 and 3-8 lack novelty and an inventive step.

CLAIM 4 of document 3 describes a preparation containing solifenacin that disintegrates in the oral cavity. Therefore, the invention of claim 1 is one and the same as the invention described in document 3. In addition, the inventions of claims 3-8 of this application are ones that specify the process for producing the invention of claim 2, but specification of the production process cannot distinguish the inventions of claims 3-8 of this application from the invention described in document 3 as a composition containing solifenacin.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/005377

Supplemental Box

In case the space in any of the preceding boxes is not sufficient. Continuation of: $Box\ V$.

[4] Based on the descriptions in documents 1-4 cited in the international search report, the inventions of claims 2-9 lack an inventive step.

Documents 1-3 describe solid pharmaceutical preparations containing solifenacin. On the other hand, the inventions of claims 2 and 9, and the inventions among claims 3-8 that are dependent on claim 2 specify the content of amorphous solifenacin, and in that respect they differ from the inventions described in documents 1-3.

However, document 4 states that the active ingredient can be converted to the amorphous form depending on the water content in a solid pharmaceutical preparation, and an amorphous form can further lead to inactivation of the active ingredient. Therefore, this authority finds that persons skilled in the art could arbitrarily focus on the amorphous form in compositions containing solifenacin and decrease the water content in the composition by various methods to decrease the content of the amorphous form.

[5] Based on the descriptions in documents 1-6 cited in the international search report, the inventions of claims 10-12 lack an inventive step.

Documents 1-3 describe solid pharmaceutical preparations containing solifenacin. On the other hand, the inventions of claims 10-12 contain an agent that inhibits the conversion of solifenacin to the amorphous form, and in that respect they differ.

However, , document 4 states that the active ingredient can be converted to the amorphous form depending on the water content in a solid pharmaceutical preparation, and an amorphous form can further lead to inactivation of the active ingredient. In addition, documents 5-6 describe the inclusion of various additives in a solid pharmaceutical preparation to prevent conversion of an active ingredient to an amorphous form due to the water content in that preparation.

Thus, this authority finds that persons skilled in the art can easily conceive of including various agents to inhibit the conversion of solifenacin to the amorphous form in the solid pharmaceutical preparations containing solifenacin described in documents 1-3.

In addition, Table 3 in the DESCRIPTION of this application states that polyethylene glycol (PEG) is preferable among the above agents to inhibit conversion to the amorphous form, but COMPARISION EXAMPLES 4 and 5, that contain an additive(s) other than PEG use much more water in the manufacturing process than EXAMPLE 5 that uses PEG.

This being the case, this authority finds that it is unclear whether the stabilizing effect shown in EXAMPLE 5 is one provided by using PEG, and therefore, based on the results in Table 3, this authority cannot find that the inventions of claims 10-12 involve an inventive step.